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Docket No. 69014-B/GJG/BJA

Oral Hearing Requested

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants	:	Kiran K. Chada et al.	
Serial No.	:	10/768,566	Group Art Unit: 1646
Filed	:	January 29, 2004	Examiner: G. Chandra
For	:	METHODS OF TREATING OBESITY AND METABOLIC DISORDERS RELATED TO EXCESS ADIPOSE TISSUE BY ADMINISTRATION OF S-FRP-5 PEPTIDE	

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Sir:

REPLY BRIEF
TO EXAMINER'S MARCH 11, 2008 ANSWER

This Reply Brief is filed in response to the Examiner's Answer issued March 11, 2008 in connection with the above-identified application. A response to the March 11, 2008 Answer is due May 11, 2008. However, since May 11, 2008 falls on a Sunday, a response filed on the next succeeding day which is not a Saturday, Sunday or Federal Holiday, i.e. Monday, May 12, 2008, is considered timely under 37 C.F.R. §1.7. Accordingly, this Reply Brief is being timely filed. No fee is deemed necessary in filing this Reply Brief. If any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

In compliance with 37 C.F.R. §41.41, and M.P.E.P. §1208(I), this Reply Brief contains an identification page (page 1) as well as separate status of the claims page (page 3), grounds of rejection to be reviewed on appeal page (page 4), and argument pages (pages 5-13).

STATUS OF CLAIMS

Claims 1, 8, 9 and 17-19 as reproduced have been entered and finally rejected solely on the ground of anticipation. Accordingly, claims 1, 8, 9 and 17-19 are pending and rejected. Claims 2-7 and 10-16 have previously been cancelled.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole issue to be reviewed, whether Appellants' claimed invention is anticipated under 35 U.S.C. §102(e) by Xu et al., U.S. Patent Application Publication No. 2003/0143610 A1, published July 31, 2003 ("Xu et al.")

Appellants' Arguments

In response to the Examiner's Answer, Appellants maintain their position that (i) Xu et al. does not teach all elements of the claimed invention; (ii) Xu et al. does not inherently disclose all elements of the claimed invention and the requirements for inherent anticipation have not been met in the rejection set forth; and (iii) Xu et al. is not an enabling disclosure for what the Examiner alleged it teaches.

Appellants note that their position iterated in the preceding paragraph applies separately to each of the rejected claims 1, 8, 9 and 17-19. Appellants further note that the arguments provided hereinbelow apply separately to each of claims 1, 8, 9 and 17-19. Thus, claims 1, 8, 9 and 17-19 do not stand together but stand separately.

Appellants maintain the argument set forth in Appellants' October 15, 2007 Appeal Brief, and further supplement it with the following reply to the Examiner's March 11, 2008 Answer.

Maintained Claim Rejections Under 35 U.S.C. 102(e)

In the March 11, 2008 Examiner's Answer the Examiner stated that "Xu et al teach administering a polypeptide SARP3 of SEQ ID NO:2 to a subject having a metabolic disorder characterized by aberrant SAPR3 polypeptide activity or aberrant SARP3 nucleic acid expression, e.g., obesity, diabetes, anorexia or cachexia, wherein a SARP3 modulator is a SARP3 polypeptide comprising the amino acid sequence of SEQ ID NO:2 [0018]."

The Examiner has mischaracterized Xu et al.

Appellants respectfully submit that the Examiner's characterization of Xu et al. relies on the teaching from Appellants' disclosure. For this reason alone, the rejection is improper.

For clarity, Appellants reproduce sentence-by-sentence, with comment, what Xu et al. recites in paragraph [0018].

> "In yet another aspect, the invention features a method for treating a subject having a metabolic disorder characterized by aberrant SARP3 polypeptide activity or aberrant SARP3 nucleic acid expression e.g., obesity, diabetes, anorexia, or cachexia." (Emphasis added.)

The foregoing sentence purports to disclose a treatment for "aberrant" SARP3 polypeptide activity or "aberrant" SARP3 nucleic acid expression, where "aberrant" must include at least more than normal and less than normal. The sentence also exemplifies treating diametrically opposed conditions in the alternative (obesity and diabetes vs. anorexia and cachexia). It is not possible to reconcile from this sentence which condition is associated with "aberrant" SARP3, which condition

is associated more SARP3 activity/expression, and which condition is associated with less SARP3 activity/expression.

The next sentence in paragraph [0018] of Xu et al. provides:

> "The method includes administering to the subject a SARP3 modulator, e.g., in a pharmaceutically acceptable formulation or by using a gene therapy vector." (Emphasis added.)

Again blurring direction, "a SARP3 modulator" can include at least something that increases as well as something that decreases SARP3.

The next and last sentence in paragraph [0018] of Xu et al. provides:

> "Embodiments of this aspect of the invention include the SARP3 modulator being a small molecule, an anti-SARP3 antibody, a SARP3 polypeptide comprising the amino acid sequence of SEQ ID NO:2 or 5 or a fragment thereof, a SARP3 polypeptide comprising an amino acid sequence which is at least 90 percent identical to the amino acid sequence of SEQ ID NO:2 or 5, an isolated naturally occurring allelic variant of a polypeptide consisting of the amino acid sequence of SEQ ID NO:2 or 5, an antisense SARP3 nucleic acid molecule, a nucleic acid molecule of SEQ ID NO: 1, 3, 4, or 6 or a fragment thereof, or a ribozyme." (Emphasis added.)

The foregoing sentence provides at least sixteen different possible types of "modulators," including "modulators" that clearly achieve different ends. For example, "an anti-SARP3 antibody" probably refers to something that will attach to and deactivate SARP3 polypeptides. Yet, the very next alternative is the "SARP3 polypeptide." The purpose of administering an antibody to a polypeptide is diametrically opposed to the

purpose of administering the polypeptide. Such disclosure is simply irreconcilable.

Another example of diametrically opposed teaching in this final sentence is "an antisense SARP3 nucleic acid molecule," immediately followed by "a nucleic acid molecule [encoding SARP3]." An "antisense" inhibits expression of the targeted nucleic acid. Again, administration of a nucleic acid is irreconcilable with administration of the antisense targeting the nucleic acid for inhibition.

Taken as a whole, paragraph [0018] of Xu et al. offers no information with respect to the role of SARP3 in any part of the listed conditions. Paragraph [0018] is a listing of diametrically opposed possibilities. Paragraph [0018], and indeed Xu et al., provide nothing more than a listing of the possible permutations of conditions and treatments, effectively <u>teaching nothing</u> about the role of SARP3 in any given condition.

Appellants submit, therefore, that the Examiner has mischaracterized what Xu et al. in fact teaches. Xu et al. certainly does not teach any method of reducing the amount of adipose tissue or adipose tissue formation, as claimed by Appellants.

In fact, the Examiner's reconstruction of Xu et al. to somehow arrive at the claimed invention is informed by *Appellants' invention* of a method of reducing the amount of adipose tissue or adipose tissue formation by increasing the amount of the sFRP-5 peptide. The Examiner's mischaracterization of Xu et al. is, therefore, clearly based on hindsight. To accentuate the correctness of this conclusion, Appellants invite someone

unfamiliar with their invention to read Xu et al. and explain how to reduce the amount of adipose tissue or adipose tissue formation.

Xu et al. Does Not Teach All The Elements Of The Claimed Invention #2.

Xu et al. does not teach the "amount" of an sFRP-5 peptide which is *effective* to reduce the amount of adipose tissue in the subject as recited by Appellants' claims.

In the March 11, 2008 Answer, the Examiner stated that "[s]ince [Appellants'] claims are not drawn to [a] degree of reduction in the amount of adipose tissue, any administration of SARP3 polypeptide would inherently meet the claim limitation." Thus, the Examiner is apparently stating that *any amount* of SARP3 is *effective* to reduce the amount of adipose tissue. But the Examiner provides no explanation for such a conclusion. Appellants respectfully maintain that any amount is not effective.

Moreover, Appellants note that the amount *effective* to achieve a previously unknown effect cannot be determined without, e.g. some experimentation where the effect can be observed.

Appellants' specification provides the relevant experimental details, including in mammals (e.g. see Fig. 7). Xu et al. does not. In fact, Xu et al. does not even disclose the concept that an sFRP-5 peptide can *reduce adipose tissue*, or that it can reduce adipose tissue *formation*. Appellants thus note that Xu et al. cannot teach the element of administering *an amount* of an sFRP-5 peptide *effective* to reduce the amount

of adipose tissue. Consequently, the Examiner has not, and cannot, point to wherein Xu et al. such is taught.

The same argument applies *mutatis mutandis* to the amount of SARP3 polypeptide effective to stimulate expression of the sFRP-5.

Accordingly, Appellants' maintain their position that Xu et al. does not teach all the elements of Appellants' invention as claimed in claims 1, 8, 9, and 17-19.

Appellants' Position That Xu et al. Is Not An Enabling Disclosure For What The Examiner Asserts It Teaches.

In response to Appellants' observation that the same Examiner has previously acknowledged that the disclosure of Xu et al. is not enabling "for a method of modulating a SARP3 mediated lipid metabolism" during the examination of the Xu et al. application, the Examiner stated that the scope of claims rejected during examination of the Xu et al. application was different to the invention being claimed in the instant application.

Appellants note, however, that in rejecting the Xu et al. application, the same Examiner stated "[g]iven the teachings of unpredictability found in the prior art, detailed teachings are required to be present in the disclosure in order to enable the skilled artisan to practice the claimed invention. These teachings are absent. There is no discussion of how SARP3 can play a role in modulating lipid metabolism." May 16, 2006 Office Action in U.S. Serial No. 10/338,604 *(Xu et al. application)* (Emphasis added.)

Accordingly, it is not tenable that Xu et al. provides an enabling disclosure of Appellants' claimed invention. The "mere naming or description of the subject matter is insufficient, if it cannot be produced without *undue experimentation*. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003)." M.P.E.P §2121.01. (Emphasis added.)

Appellants also note that the Examiner stated in the March 11, 2008 Answer that Xu et al. "did not file a response back against the office action, and therefore, there was not a final decision that the reference Xu et al is not enabling." Appellants note, however, that regardless of whether Xu et al. could have rebutted the Examiner's conclusion that Xu et al. does not contain any "discussion of how SARP3 can play a role in modulatory lipid metabolism," the Examiner's Answer does not rebut such conclusion.

The Examiner's conclusion in the May 16, 2006 Office Action in the Xu et al. application is directly relevant to the subject application and remains unrebutted on the record. By failing to provide a "discussion of how SARP3 can play a role in modulating lipid metabolism," Xu et al. fail to enable a method for modulating lipid metabolism based on SARP3. Therefore, Xu et al. cannot enable one skilled in the art to practice Appellants' claimed method (assuming *arguendo* such a method is disclosed in Xu et al).

To enable Appellants' claimed method, Xu et al. would need to teach one of skill in the art the role of SARP3 in lipid metabolism. Xu et al. does not provide such a teaching.

The same argument applies *mutatis mutandis* as to Xu's lack of enablement regarding a method to stimulate expression of the sFRP-5.

Accordingly, Appellants' maintain their position that Xu et al. is not an enabling disclosure for what the Examiner claims it teaches.

SUMMARY

For the foregoing reasons, Appellants submit that the Examiner's rejections of claims 1, 8-9 and 17-19 are erroneous, and respectfully submit that the rejections of these claims should be reversed.

Respectfully submitted,

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